Remarks

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 51-82, 92 and 93 are now pending in this application. Support for the claim amendments and new claims 92 and 93 can be found throughout the patent application, for example at page 27, lines 4 to 26. Accordingly the amendments and new claims raise no issue of new matter.

Because of claim amendments, Applicants reserve the right to argue priority to parent application, 08/742,255, filed 31 October 1996, should an issue of such arise.

Applicants note for the record that claims 53, 59, 60, 64 and 65 have been rejected only on the grounds of obviousness-type double patenting.

Rejection of Claims 51-52, 54-58, 61-63, 66-68, 70-74, 77-79, and 82 under 35 U.S.C. §102(b) over Bogart (U.S. Patent 5,468,606).

Claims 51-52, 54-58, 61-63, 66-68, 70-74, 77-79, and 82 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Bogart (U.S. Patent 5,468,606). This rejection is respectfully traversed.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the

applicant to rebut the *prima facie* case. *See, e.g., In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The present claims recite a support having an attachment layer comprised of diamond-like carbon, wherein the attachment layer captures the analyte of interest for detection by binding the analyte directly to the diamond-like carbon. It is fundamental that the attachment layer have access to the analyte sample for analyte to bind to the diamond-like carbon.

It is respectfully submitted that no prima facie rejection has been established for anticipation because the Examiner has failed to consider the claim limitation which requires that the attachment layer be adapted for capture of the analyte of interest for detection in the assay by binding the analyte directly to the diamond-like carbon. As best as Applicant can determine, the Examiner seems to assert that Bogart et al. teaches an attachment layer made of diamond like carbon ("[Bogart teaches] an attachment layer comprising a diamond layer on the surface." ; Office Action, page 4). The alleged support for this conclusion is asserted to be found in Bogart at Col. 3, lines 13-40; Col. 5, lines 27-45; Col. 8, lines 31-44, and claim 7.

Regarding Col. 3, lines 13-40 of Bogart, there is no mention whatsoever of any attachment layer (or anti-reflective layer). Further, regarding Col. 5, lines 27-45 of Bogart (copied below) , there is no mention of any attachment layer made of diamond. Diamond is discussed as seen below in the first paragraph dealing with an anti-reflective layer, while the attachment layer is discussed in the second paragraph.

> In yet other aspects, the invention features an optical assay device for detection of an analyte formed with a substrate selected from glass, plastic, silicon and amorphous silicon, an anti-reflective layer selected from silicon nitride, composite of silicon/silicon dioxide, titanates, silicon carbide, **diamond**, cadmium sulfide, and titanium dioxide, an attachment layer selected from a polymeric silane, polymeric siloxanes, film forming latex, or a dendrimer, and a specific binding layer for the analyte.

> In preferred embodiments, the amorphous silicon layer has a thickness between about 900 and 1100 nm; an aluminum layer of between about 1800 and 2200 Å thickness is provided on the glass; the silicon nitride, composites of silicon/silicon dioxide, titanates, or titanium dioxide layer has a thickness between about 480 and 515 Å; the **attachment layer** is an aminoalkyl-T-structured branched siloxane of between about 90 and 110 Å thickness; and the receptive material is an antibody layer of between about 30 and 60 Å thickness.

Regarding Col. 8, lines 31-44 of Bogart, there is no mention whatsoever of any attachment layer (or anti-reflective layer) or diamond (the cited text discusses an instrument that detects light using Brewster's angle).

Regarding Claim 7 of Bogart, this claim makes no reference to any attachment layer; Rather, claim 7 refers to an antireflective film made from diamond and other materials. Furthermore, claim 1 (from which claim 7 depends) clearly indicates that the anti-reflective layer is below the attachment layer.

Thus, there is nothing in any of the cited passages of Bogart or Claim 7 of Bogart to support the Examiner's assertion that this reference teaches diamond as an attachment layer.

The Examiner is correct that Bogart teaches an anti-reflective layer made of diamond. However, in all cases, such anti-reflective layer is below the attachment layer (see e.g., col. 5, lines 24-24; "an attachment layer is interposed between the optical material and the receptive material."). Because the diamond anti-reflective layer in Bogart et al. is always below the attachment layer, the former would not have access to analyte and thus cannot bind analyte as required in the presently claimed device.

Nowhere in any of the prior Office Actions has the Examiner indicated how the anti-reflective layer in the devices of Bogart et al. can bind to analyte if the anti-reflective layer if it is below and covered over by an attachment layer. The Examiner argues at page 6 that Bogart et al.

teaches that the attachment layer promotes binding of analyte, however this is of no moment because the attachment layer in Bogart et al. is not made of diamond or diamond-like material.

The Examiner argues at page 6 that open claim language encompasses any additional components of the Bogart et al. attachment layer. Whether or not correct, this argument is unavailing because there is no diamond or diamond like carbon in the attachment layer of Bogart. It is improper for the Examiner to combine elements of the attachment layer and the anti-reflective layer of Bogart et al. in order to make the rejection. Use of open claim language does not sanction such an approach.

As a final point, the Examiner asserts that Applicant admits that Bogart at Col. 5, lines 15-35 teaches diamond like carbon on the support surface. The cited passage, however, supports no such reading.

> In preferred embodiments, the device has an anti-reflective layer attached to the upper substrate surface, having an optical material able to attach to the upper substrate surface, and **a receptive material positioned most remote from the upper substrate surface** and selected from materials specific to bind the analyte of interest in a fluid to be tested; the base material is selected from any of the group consisting of glass, fused silica, plastics, semiconductors, ceramics, and metals, and may be either rigid or flexible; and **an attachment layer is interposed between the optical material and the receptive material**.
>
> In yet other aspects, the invention features an optical assay device for detection of an analyte formed with a substrate selected from glass, plastic, silicon and amorphous silicon, an anti-reflective layer selected from silicon nitride, composite of silicon/silicon dioxide, titanates, silicon carbide, diamond, cadmium sulfide, and titanium dioxide, **an attachment layer selected from a polymeric silane, polymeric siloxanes, film forming latex, or a dendrimer**, and a specific binding layer for the analyte.

As seen in the first paragraph, the receptive material is most remote and the attachment layer is directly underneath. Furthermore, the second paragraph identifies various substances for the

attachment layer, none of which include diamond or diamond like carbon. In fact, the text directly above indicates that the anti-reflective material may be made of diamond. Thus, there is nothing to support any such alleged admission that Bogart at Col. 5, lines 15-35 teaches diamond like carbon on the support surface.

Accordingly, as Bogart et al. fails to anticipate the claims, reversal of the rejection is respectfully requested.

Rejection of claims 67-68, 71-67 and 82 under 35 U.S.C. §103(a) over Kobashi in view of Bogart.

The Examiner rejects claims 67-68, 71-67 and 82 under 35 U.S.C. 103(a) as allegedly being unpatentable over Kobashi in view of Bogart. This rejection is respectfully traversed.

In order to establish a prima facie case of obviousness, it is necessary that the prior art disclose each and every limitation of the claim, that there is a reasonable expectation of success, and that there is some motivation, either in the prior art references or in the knowledge of the person of ordinary skill in the art, to make the asserted combination or modify or combine the reference teachings (MPEP 2142).

The present claims are directed to a support having an attachment layer comprised of diamond-like carbon, wherein the attachment layer captures the analyte of interest for detection by binding the analyte directly to the diamond-like carbon. The claims also specify the thickness of the diamond-like carbon attachment layer as between about 50 Å to about 500 Å. The claims further exclude attachment layers made from synthetic diamond, natural diamond, industrial diamond, monocrystalline diamond, resin type diamond, polycrystalline, and crystalline carbon.

Kobashi discloses various ranges of thicknesses for the different applications of diamond layers, with the thinnest layer contemplated in Kobashi being 0.1 to 50 μM (1,000 to 500,000

angstroms). Kobashi also notes that the thickness of diamond is suggested from "a viewpoint of performance and cost." (Col. 7, line 15). The Examiner emphasizes that, in addition to performance, the Kobashi reference considers cost as a factor in determining the range of diamond film thicknesses and thus alleges that the Kobashi reference does not teach or suggest that a diamond layer that is thinner than 1,000 angstroms would not work as an electrode.

The Examiner acknowledges that Kobashi does not teach a thickness for the diamond layer that overlaps the range of 50-500 angstroms recited in the instant claims (the lower limit thickness specified in Kobashi is 1,000 angstroms, twice the upper limit thickness claimed by Applicant). The Examiner asserts at page 8 of the Office Action that the missing teaching is well known in the art and turns to Bogart et al. to support this contention as shown below.

> Bogart et al. teach a similar support comprising a surface comprising **an attachment layer comprising a layer of diamond-like carbon** on the surface of between about 50 to about 500 Å (column 5, lines 40-42 and column 25, lines 32-37) wherein the claimed thickness is the preferred thickness for attachment layers.

It is respectfully submitted that this cannot support the rejection because any alleged assertion that Bogart teaches an attachment layer comprising a layer of diamond-like carbon is wholly untenable as discussed extensively above under the rejection for anticipation.

The Examiner also asserts at the text bridging pages 8 and 9 of the Office Action that Kobashi "does not teach or suggest that other thicknesses would not work, but merely suggests that when considering performance **and costs** a range of thicknesses are suggested." (emphasis in the original). However, the Examiner fails to recognize that in attempting to minimize cost, a skilled artisan would be motivated to use a diamond film that is as thin as possible to avoid wasting this expensive material. If the diamond layer is made to thin, its performance will suffer. Hence, Kobashi is referring to cost in regard to the upper limit of the thickness range of the diamond film and performance with regard to the lower limit of thickness. Because the lower limit thickness in Kobashi would be understood to refer to a performance barrier, one of ordinary skill would not be motivated to reduce thickness lower than what is specified by Kobashi.

Accordingly, on this basis alone, the presently claimed invention is not obvious over Kobashi in view of Bogart.

Furthermore, the claims expressly exclude attachment layers made from synthetic diamond, natural diamond, industrial diamond, monocrystalline diamond, resin type diamond, polycrystalline, and crystalline carbon. These excluded materials are diamond based materials, recognized in the art as distinct from diamond like carbon (DLC). The art teaches that DLC is an amorphous material that exhibits many properties of diamond such as high hardness, high wear resistance and low friction coefficient, chemical inertness, high electrical resistance, and optical transparency in the visual and infrared. *See* Grill A., IBM Journal of Research and Development, Vol. 43, 1/2, 1999 at page 1 (attached). In contrast, diamond is a crystalline material composed of tetrahedrally coordinated sp^3-bonded carbon that exhibits long range order (*See* Grill A., IBM Journal of Research and Development, Vol. 43, 1/2, 1999 at page 1 and Choi *et al.*, US patent No 5,883,769 at column 3 lines 37 to 67; of record). Diamond films are composed of diamond microsatellites up to tens of microns in size and are constituted of a well-defined material with fixed properties (Grill A., IBM Journal of Research and Development, Vol. 43, 1/2, 1999 at page 1). In contrast DLC and DLC films lack any long range order and contain a mixture of sp^3, sp^2 and sometimes sp^1-coordinated carbon atoms in a disordered network (*See* Grill A., IBM Journal of Research and Development, Vol. 43, 1/2, 1999 at page 1 and Choi *et al.*, US patent No 5,883,769 at column 3 lines 37 to 67).

The Kobashi reference discloses the use of diamond films for use as electrodes in biosensors. The diamond films that are suitable for the devices disclosed in the Kobashi reference are described at column 15 line 58 to column 16 line 34 as follows:

> Diamond films described above can be those deposited by vapor-phase synthesis on the surface of natural or man-made bulk diamond crystal substrate. They can also be ordinary polycrystalline diamond films, highly oriented diamond films, and heteroepitaxial diamond films deposited on non-diamond substrates, such as silicon, silicon nitride, silicon carbide, refractory metals, and the like.

> Since the chemical reactivity and the surface structure of diamond are different for different crystal planes, the diamond surface for the biosensor must be carefully selected for chemical modification and binding of functional molecules, and hence for the best sensor performance. In the present invention, it was found that biosensors with a good linearity in the current-voltage characteristic and a good signal-to-noise ratio are achieved, if the diamond film surface consists of either (111) or (100) crystal faces.

The Kobashi reference contemplates different types of **diamond** films, but does not teach or suggest using **DLC**. In fact, Kobashi specifically excludes the use of DLC by requiring that "the diamond film surface consists of either (111) or (100) crystal faces," a property of diamond films, not DLC films.

Thus, Kobashi does not teach or suggest the use of any DLC materials, such as are encompassed by the claims at issue. Furthermore, the claims at issue do not read on any diamond material that is taught by Kobashi. As noted, claim 67 and dependent claims exclude attachment layers made of synthetic diamond, natural diamond, industrial diamond, monocrystalline diamond, resin type diamond, polycrystalline, or crystalline carbon. Likewise, Bogart contemplates the use of diamond as a material for an antireflective layer, but does not teach or suggest using DLC anywhere in the device.

Thus, the Kobashi and Bogart references, both alone and in combination, fail to meet all the limitations of the instant claims and therefore a *prima facie* case of obviousness fails to be established based on these references.

Rejection of claims 69 and 70 under 35 U.S.C. §103(a) over Kobashi in view of Bogart and Yu (U.S. Patent No. 5,273,788)

The rejection of claims 69 and 70 under 35 U.S.C. 103(a) as allegedly being unpatentable over Kobashi in view of Bogart, and further in view of Yu (U.S. Patent No. 5,273,788) is respectfully traversed.

First, it is respectfully submitted that the Yu reference fails to cure the deficiencies noted in the combination of Kobashi and Bogart. As mentioned above, the claims specify the thickness of the diamond-like carbon attachment layer as between about 50 Å to about 500 Å and the claims exclude attachment layers made from synthetic diamond, natural diamond, industrial diamond, monocrystalline diamond, resin type diamond, polycrystalline, and crystalline carbon. Thus, the present rejection fails at the outset. Furthermore, as discussed below, the Yu reference also fails to support the teaching that it was alleged to provide.

Claim 69 is directed to a support according to claim 67, wherein the attachment layer has a degree of hydrophobicity resulting from a preselected sp^2 and sp^3 character of the diamond-like carbon. The Examiner acknowledges that Kobashi is silent regarding the control of hydrophobicity resulting from variations in the sp^2 and sp^3 character of the diamond layers. The Examiner turns to the Yu patent, column 3, lines 15-35 and column 3 line 45 to column 4 lines 16 for this missing teaching.

The Yu reference describes a method (the Langmuir-Blodgett technique) for producing DLC with a higher proportion of carbon four fold diamond coordination (i.e. sp^3; column 3, lines 64 to 65) which permits "a better degree of control over the DLC film formation than prior art methods" (column 4, lines 15 to 16). Yu teaches that surfactant-type organic molecules with hydrophobic character are useful in the Langmuir-Blodgett technique of forming a diamond-like carbon layer. Such surfactant-type organic molecules having nothing whatsoever to do with the sp^2 and sp^3 ratio of the film and its relation to the hydrophobicity of a DLC film.

Thus, none of the three references in the combination teaches an attachment layer that has a degree of hydrophobicity resulting from a preselected sp^2 and sp^3 character of the diamond-like carbon. Motivation to combine also would be absent because only one of the references teaches anything about DLC layers. Accordingly, reconsideration and withdrawal of the rejection of claim 69 is respectfully requested.

Claim 70 is directed to a support according to claim 67, wherein diamond-like carbon is used as a antireflective layer. The Kobashi reference uses diamond film as electrodes and a skilled artisan would not be motivated to use "diamond-like carbon" as electrodes for the reasons discussed above. Thus, there would be no motivation to combine the Koabshi and Yu references for the purpose of making the device disclosed in Kobashi modified with a diamond-like carbon layer taught by Yu. Therefore, the rejection of claim 70 as obvious over Kobashi in view of Bogart, and further in view of Yu fails to achieve a *prima facie* case of obviousness.

Rejection of claims 77-79 under 35 U.S.C. §103(a) over Kobashi in view of Bogart and Turner (U.S. Patent No. 5,624,537)

The rejection of claims 77-79 under 35 U.S.C. §103(a) as allegedly being unpatentable over Kobashi in view of Bogart, and further in view of Turner (U.S. Patent No. 5,624,537) is respectfully traversed.

The Turner reference discloses a biosensing system that comprises a permeable membrane, a porous protein-receiving matrix and an electrode. Thus, the Turner reference fails to cure the deficiencies noted in the combination of Kobashi and Bogart. As mentioned above, the claims specify the thickness of the diamond-like carbon attachment layer as between about 50 Å to about 500 Å and the claims exclude attachment layers made from synthetic diamond, natural diamond, industrial diamond, monocrystalline diamond, resin type diamond, polycrystalline, and crystalline carbon. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of claims 80 and 81 U.S.C. §103(a) over Kobashi in view of Bogart and Choi (U.S. Patent No. 5,883,769).

The rejection of claims 80 and 81 U.S.C. 103(a) as allegedly being unpatentable over Kobashi in view of Bogart, and further in view of Choi (U.S. Patent No. 5,883,769) is respectfully traversed.

The Choi reference describes a video cassette recorder head drum that is coated with a protective layer comprising diamond-like carbon. The reference compares the properties of diamond and diamond-like carbon. The Examiner alleges that the properties of the **diamond** film disclosed in Kobashi would meet the hardness properties of diamond-like carbon as described in the Choi reference.

However, as Kobashi does not teach or suggest diamond-like carbon films, the hardness values described by Choi et al. would not be applicable. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Obviousness Type Double Patenting

The Examiner has rejected claims 51- 52, 54-60, 66-68, 70-76 and 82 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1,7, 9 and 13 of U.S. Patent No. 5,468,606. This rejection is respectfully traversed. The instant claims are directed a support with a surface comprising attachment layer comprising diamond-like carbon. The claims of the '606 patent state that the "attachment layer is amino-alkyl-T-structured branched siloxane..." The two types of materials renders the claims patentably distinct. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 51-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7, 11, 23-34 and 38-50 of copending Application No. 08/950,963. The Applicant will submit a terminal disclaimer if the claims in the copending case are advanced to issue in their present form, and the claims in the present are otherwise allowable in their present form.

Conclusion

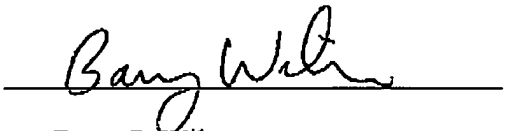
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested and that the rejections be withdrawn.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date September 16, 2004

By 

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